



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,328	04/24/2001	Y. Tom Tang	PF-0628 USN	6729
22428	7590	10/20/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			LOCKARD, JON MCCLELLAND	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,328

Applicant(s)

TANG ET AL.

Examiner

Jon M Lockard

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 16 July 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group VIII, Claims 3-6, 12-14 (each in part), as they pertain to polynucleotides encoding the polypeptide of SEQ ID NO:2; and claims 9-11 (each in part), as they pertain to SEQ ID NO:4, drawn to polynucleotides, vectors, host cells, and methods of producing the polypeptide, in the reply filed on 13 July 2004 is acknowledged. The traversal is on the ground(s) that additional examination of Group VII is not unduly burdensome. This is not found persuasive because Group VII is drawn to polypeptides and Group VIII is drawn to nucleic acids. Each group represents an independent and distinct invention. Group VII is a protein art invention and Group VIII is a nucleic acid art invention, which are structurally and functionally different compounds. Each group has a different class and subclass (514/12 for Group VII and 536/23.5 for Group VIII) and would require non-overlapping sequence searches. Applicants further traverse on the grounds that the unity of invention standard must be applied in national stage applications. The Examiner agrees with this fact and would like to remind the Applicants that 371 practice for unity of invention was followed in the previous Office Action. As set forth in the previous Office Action, mailed 13 May 2004, lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility. The requirement is still deemed proper and is therefore made FINAL. Claims 1-2, 7-8, and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 3-6, 12-14 (each in part), as they pertain to

Art Unit: 1647

polynucleotides encoding the polypeptide of SEQ ID NO:2; and claims 9-11 (each in part), as they pertain to SEQ ID NO:4, drawn to polynucleotides, vectors, host cells, and methods of producing the polypeptide are currently under examination.

2. The requirement is still deemed proper and is therefore made FINAL.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

4. It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/US99/25499 and US provisional application No. 60/172,249, filed 29 October 1999 and 29 October 1998, respectively. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional US applications. Also, the current status of all nonprovisional parent applications referenced should be included.

5. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application

Art Unit: 1647

filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Information Disclosure Statement

6. The information disclosure statement (IDS), filed 16 July 2004, has been considered by the examiner.

Drawings

Art Unit: 1647

7. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R. §§1.821-1.825 will be published as part of the patent. Therefore, it is unnecessarily redundant to repeat the sequence information in the form of Figures. Applicants should amend the specification to delete any Figures (e.g. Figures 1 and 2) which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Specification

8. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 10, lines 18 and 23). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

9. Claims 3-6 and 9-14 are objected to because of the following informalities: Claims 1 and 9 encompass non-elected inventions, e.g., SEQ ID NO:1 in claim 1 and SEQ ID NO:3 in claim 9. Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 35 USC §112

35 U.S.C. 101 reads as follows:

Art Unit: 1647

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

11. The instant application discloses a polynucleotide set forth as SEQ ID NO:4 encoding a protein set forth as SEQ ID NO:2, polynucleotides encoding fragments of the protein of SEQ ID NO:2, polynucleotide variants having at least 70% sequence identity to SEQ ID NO:4, the polynucleotide encoding SEQ ID NO:2, or fragments thereof, and a method of producing the proteins. The specification asserts that the instant application relates to a human transmembrane 4 protein (TM4P) derived from a kidney tissue cDNA library (see page 18, lines 14-16). The specification discloses that Northern analysis revealed the expression of SEQ ID NO:4 in various libraries, including libraries associated with cancer, inflammation, developmental or proliferating tissues, cardiovascular tissues, gastrointestinal tissues, urologic tissues, and reproductive tissues (see page 19, lines 4-9). However, the instant specification does not teach any physiologic ligands or functional characteristics of the TM4P set forth in SEQ ID NO:2 or encoded by the disclosed nucleic acid set forth in SEQ ID NO:4. Further, the TM4P comprising SEQ ID NO:2 or encoded by said disclosed nucleic acid has never been expressed in a cell or organism or

Art Unit: 1647

assayed for functional activity. The amino acid for set forth in SEQ ID NO:2 has been deduced from the nucleic acid sequence (see page 44, lines 28-34). There is no well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention.

12. The specification asserts the following as patentable utilities for the claimed receptor protein and partial peptides of SEQ ID NO:1 and the DNA encoding the receptor protein or the partial peptides:

- 1) The polypeptide (SEQ ID NO:2) encoded by SEQ ID NO:4 or a vector capable of expressing the polypeptide can be used to treat or prevent a variety of disorders associated with decreased expression or activity of SEQ ID NO:2 (pg 28, lines 4-33);
- 2) A vector expressing the complement of the polynucleotide of SEQ ID NO:4 may be administered to treat or prevent a variety of disorders that may be associated with increased expression or activity of the polypeptide of SEQ ID NO:2 (pg 29, lines 16-18);
- 3) The polynucleotides encoding SEQ ID NO:2, or any fragment or complement thereof, may be used for therapeutic purposes (pg 31, line 33- pg 33, line 32);
- 4) The polynucleotides may be used to detect and quantify gene expression in biopsied tissues in which expression may be correlated with a disease (pg 37, lines 13-17);
- 5) The polynucleotides may be used in diagnostic assays to monitor regulation of TM4P levels during therapeutic intervention (pg 37, lines 17-18);
- 6) The polynucleotides may be used as probes (pg 37, lines 19-25);
- 7) The polynucleotides may be used for the diagnosis of disorders associated with expression of TM4P (pg 38, line 3 - pg 39, line 32);
- 8) The polynucleotide of SEQ ID NO:4 or fragments thereof may be used as primers for PCR (pg 39, line 32 – pg 40, line 4);
- 9) The oligonucleotides or longer fragments of SEQ ID NO:4 may be used as targets in a microarray (pg 40, lines 12-17);
- 10) The polynucleotides may be used in mapping the naturally occurring genomic sequence (pg 40, line 23 – pg 41, line 15); and

Art Unit: 1647

11) The polynucleotides or fragments thereof may be used in the construction of recombinant protein expression systems (pg 22, lines 2-6).

13. These asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a “real world” context of use. Novel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific, substantial, and credible utility. The specification neither identifies the biological functions of the claimed DNA and the protein encoded by it, nor any diseases that are associated with the claimed molecules. Without any biological activity or link to a disease, such constitutes further research to determine the properties of the claimed TM4P protein or partial peptides encoded by SEQ ID NO:4, which is insufficient to meet the requirement of 35 USC § 101.

14. These activities and functions are conjectural and are based solely on the identification of SEQ ID NO:2 as being a transmembrane 4 protein (TM4P). While it is credible that SEQ ID NO:2 is a TM4P, its identification as such is not sufficient to establish either a well known, or a specific, substantial and credible utility. There is no ligand identified that binds to it, no signaling pathway with which it is involved, and no disease or disorder correlated with the polypeptide. Since the instant specification does not disclose how to use the polypeptide of SEQ ID NO:2, a skilled artisan would not know how to use nucleic acids encoding the polypeptide (SEQ ID NO:4).

15. The art teaches that the tetraspanin family is diverse, with at least 28 distinct family members in mammals, and that function cannot be predicted merely by identifying a protein as a tetraspanin. For example, Yunta et al. (2003, Cellular Signalling 15:559-564), teach that individual tetraspanin proteins can interact with several types of proteins, most of which play a

Art Unit: 1647

receptor role, or alternatively, couple receptors to signaling pathways. These interacting proteins range from membrane receptors, adhesion molecules, to signal transduction molecules (see pages 559-560, Table 1). They also state that some of these protein-protein interactions are restricted to a specific tetraspanin (see pg. 560). Lastly, Yunta et al. state that the heterogeneity and flexibility in assembling protein complexes containing tetraspanin proteins can account for the very different biological effects reported for tetraspanins (see page 563). Thus, although the homology of the tetraspanin family allows identification of such as tetraspanins, such is not predictive of function. It is possible that, after further characterization, this nucleic acid and the protein encoded by it might be found to have a patentable utility, in which case proteins would have a specific utility, or the protein might be found to be associated with a specific disease.

16. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed “real world” utility. The instant claims are drawn to a protein which has undetermined function or biological significance. Until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:1 or the polynucleotide encoding it (SEQ ID NO:2, the claimed invention is incomplete.

17. Claims 3-6 and 9-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

18. Furthermore, even if the protein of SEQ ID NO:2 or the DNA of SEQ ID NO:4 that encodes SEQ ID NO:2 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

19. Claim 1, from which claims 3-6 depend, recites a protein fragment of SEQ ID NO:2 with no requirement for conserved structure or function. Claims 3-6 and 9-14 recite a DNA that encodes the protein or protein fragment of claim 1, is a variant having at least 70% sequence identity to SEQ ID NO:4 or a fragment thereof, or hybridizes to the DNA encoding the protein of claim 1 or a fragment thereof, or is complementary to SEQ ID NO:4 or the polynucleotide that encodes the protein, or a fragment thereof. However, other than the protein of SEQ ID NO:2 and the DNA of SEQ ID NO:4 that encodes the protein, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure has not shown (1) which portions of SEQ ID NO:2 are critical to the activity of the protein of SEQ ID NO:2 (which is itself unknown); (2) what modifications (e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:2 that will result in protein variants or fragments with the same activity as the protein of SEQ ID NO:2; and (3) any guidance on how to use partial peptides of SEQ ID NO:2

Art Unit: 1647

which would, based on the language of said claims, encompass both active and inactive variants of SEQ ID NO:2, or the nucleic acids that encode the aforementioned peptides. The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship and can only tolerate only relatively conservative substitutions or no substitutions (See Wells, 1990, *Biochemistry* 29:8509-8517; Ngo et al., *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, pp. 492-495). Furthermore, there are five distinct regions of tetraspanins that have been identified, in which structural alterations are linked to specific functional consequences (Reviewed in Stipp et al., 2003, *Trends in Biochemical Sciences* 28(2):106-112).

20. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of substitutions/deletions on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

21. Claims 3-6 and 9-14 are also rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 1647

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

22. The specification discloses a protein of SEQ ID NO:2 and a nucleic acid sequence of SEQ ID NO:4 that encodes the protein of SEQ ID NO:2. However, Claim 1, from which claims 3-6 depend, recites a protein fragment of SEQ ID NO:2 with no requirement for conserved structure or function. Claims 3-6 and 9-14 recite a DNA that encodes the protein or protein fragment of claim 1, is a variant having at least 70% sequence identity to SEQ ID NO:4 or a fragment thereof, or hybridizes to the DNA encoding the protein of claim 1 or a fragment thereof, or is complementary to SEQ ID NO:4 or the polynucleotide that encodes the protein, or a fragment thereof. The claims do not require that the proteins and nucleic acids possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of DNA molecules.

23. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. Furthermore, the only factor present in claim 5 is a mere chemical property of the DNA in the form of a recitation of hybridizes to the polynucleotide encoding the protein of SEQ ID NO:2 or its fragments. The specification does not identify any particular portion of the structure that must be conserved, nor does it provided any disclosure of a particular structure/function correlation or biological

Art Unit: 1647

activity. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is a polynucleotide represented by SEQ ID NO:4 and a polypeptide encoded by SEQ ID NO: 4. Accordingly, the specification does not provide adequate written description of the claimed genus.

24. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

25. With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and DNA molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

26. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Art Unit: 1647

27. Therefore, only the protein of SEQ ID NO:2 and the DNA encoding the protein (SEQ ID NO:4), but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

28. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

29. Claim 3, which is dependent upon claim 1, is indefinite for reciting "fragments thereof". Without knowing the minimum length of the "fragment" of the polypeptide of claim 1 that is encoded by the polynucleotide of claim 3, the metes and bounds of the claim cannot be determined. Claims 4-6 are also rejected as they are either directly or indirectly dependent upon claim 1.

30. The term "variant" in claims 4 and 10 is a relative term which render the claims indefinite. The term "variant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The discussion of such at pages 16-17 of the

Art Unit: 1647

Specification regarding the term “variant” is noted but vague, fails to breathe life and meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claims definite.

31. Claim 5 is indefinite as there is no limiting definition of stringent hybridization conditions in the Specification, and the metes and bounds of that which will hybridize are dependent upon the conditions under which the hybridization is performed. The discussion of such at pages 12-13 of the Specification is noted but vague, fails to breathe life and meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claim definite.

32. The metes and bounds of the term “complementary” used in claims 6 and 11 are not clear from the prior art or the Specification. It is not clear if a full-length or partial complement is intended.

33. Claim 9 is indefinite for reciting “fragments thereof”. Without knowing the minimum length of the “fragment” of the polynucleotide, the metes and bounds of the claim cannot be determined. Claims 10-14 are also rejected as they are either directly or indirectly dependent upon claim 9.

34. Claim 12 is further indefinite for reciting “at least a fragment” of the polynucleotide of claim 3 (See 112¶2 rejection *supra*). Without knowing the minimum length of “at least a fragment” of the polynucleotide of claim 3, which encodes a “fragment” of the polypeptide of claim 1, the metes and bounds of the claim cannot be determined. Claims 13-14 are also rejected as they are either directly or indirectly dependent upon claim 12.

Claim Rejections - 35 USC § 102

Art Unit: 1647

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Eaton et al. (US 2003/018056 A1, published on 25 September 2003; priority date, 8 October 1998).

36. Eaton et al. teach a transmembrane protein with an amino acid sequence that is 100% identical to SEQ ID NO:2 of the Instant Application (See SEQ ID NO:108, Figure 108, and attached sequence alignment) and the cDNA which is 99% identical to SEQ ID NO:4 of the Instant Application that encodes the transmembrane protein (See SEQ ID NO:107, Figure 107, and attached sequence alignment) and fragments thereof. Eaton et al. also teach nucleic acids that are complementary to the nucleic acid set forth as SEQ ID NO:107 and the nucleic acid encoding the polypeptide of SEQ ID NO:108, and fragments thereof (See page 2, ¶0009). This cDNA, which is 99% identical to SEQ ID NO:4 of the Instant Application, would also hybridize to SEQ ID NO:4 under stringent conditions. Eaton et al. also teach a vector and a host cell comprising the cDNA that encodes the transmembrane protein, and a method of producing the transmembrane protein (see, for example, claims 17, 19-20, and page 4, ¶0023). Thus, the reference of Eaton et al. meets all the limitations of claims 3-6 and 9-14.

Art Unit: 1647

37. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al. (US 2002/0173635 A1, published on 21 November 2002; priority date, 10 April 1997).

38. Jacobs et al. teach an isolated and purified polynucleotide that shares 96% sequence identity with bp 1020-1457 SEQ ID NO:4 of the Instant Application (See SEQ ID NO:1382 and attached sequence alignment) and therefore encodes a protein comprising multiple fragments of SEQ ID NO:2 of the Instant Application. Jacobs et al. also teach nucleic acids that are complementary to the nucleic acid set forth as SEQ ID NO:1382 (See page 21, ¶0029). This cDNA, which is 96% identical to SEQ ID NO:4 of the Instant Application, would also hybridize to SEQ ID NO:4 under stringent conditions. Eaton et al. also teach a vector and a host cell comprising the polynucleotide, and a method of recombinantly producing the protein (see, for example, page 22, ¶0032-0033). Thus, the reference of Eaton et al. meets all the limitations of claims 4-6 and 9-14.

Summary

39. No claim is allowed.

Art Unit: 1647

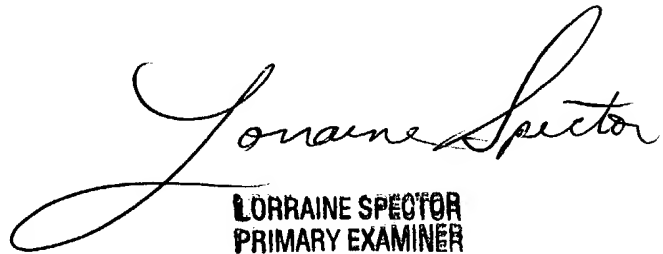
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
October 12, 2004


LORRAINE SPECTOR
PRIMARY EXAMINER